

REMARKS

I. Status of the Claims

Claims 14-22 were pending at the time of the Action. Claims 14-17 and 20-22 have been amended. Claims 23-29 have been added. Support for the phrase “a sequence having at least 95% identity...” in claim 14, can be found at page 7, line 3. Support for the phrase including the retention of “a biological function of an alpha subunit of a sodium channel” in claims 15 and 16, can be found, for example, at page 17, line 26 to page 18, line 21 and more particularly at page 17, line 28 to page 18, line 1; at page 19, line 20 to page 20, line 19; and at page 23, lines 13-19. Support for new claims 23-28, which depend directly or indirectly from claim 14, can be found in the specification, for example, at pages 52 and 54-57 (Examples 3 and 6, respectively), and in Figure 3. Support for new claim 29 can be found in the specification, for example, at Figure 2 and in the sequence listing.

Claims 14-29 are now pending.

II. Amendments to the Specification

In the specification, minor clerical errors have been corrected in page 52, line 3 (from instead of form) and page 58, line 15 (rat instead of rate). No new matter has been added.

III. Claim Objections

Claims 14-16 are objected to because they recite non-elected subject matter.

Applicants have elected examination of SEQ ID NO: 1 with traverse. Applicants maintain that the sequences of claim 15, share the unifying concept of being related to SEQ ID NO:1. The present election is made without prejudice or disclaimer as to any non-elected subject matter. Applicant specifically reserves the right to file one or more divisional applications directed to the non-elected subject matter.

Claim 14 and claim 15 are currently directed to SEQ ID NO:1. Furthermore, claim 16 is currently directed to SEQ ID NO:3. Claims 14 – 16 as they currently stand are directed to elected sequence identifiers. Therefore, the objection to claims 14 – 16 is moot.

IV. Claim Rejections Under 35 U.S.C. § 101

Claims 20, 21, and 22 are rejected as being directed to non-statutory subject matter.

Claims 20, 21, and 22 are direct to “An isolated cell.” Therefore, pending claims 20, 21, and 22 are directed to statutory subject matter and the rejection under 35 U.S.C. § 101 is moot.

V. Rejections under 35 U.S.C. § 112

A. Claims 14 – 22 satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph

Claims 14-22 are rejected under 35 U.S.C. § 112, first paragraph as not complying with the enablement requirement. Specifically, the claims are rejected based on alleged insufficient enablement for all fragments, functional derivatives, or allelic variants.

To satisfy the enablement requirement the claimed invention must be described in a way to enabled any person skilled in the art to make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Claim 14 is directed to a nucleic acid sequence selected from the group consisting of (a) the nucleic acid of SEQ ID NO:1; (b) a complement of (a); and (c) a nucleic acid sequence having at least 95% identity to the nucleic acid sequence in (a) or (b). The rejection of claim 14 is moot.

Claims 15 and 16 are directed to a fragment, functional derivative or allelic variant that “retains a biological function of an alpha subunit of a sodium channel.” In view of these current claims, the state of the art, and the guidance from the specification on the types of assays which could be used to identify fragments, derivatives or variants which retain a biological activity of

an alpha subunit of a sodium channel (as described at page 37, lines 12 to page 43, line 13; from page 44, line 27 to page 50, line 4; and in example 7), it is respectfully submitted that claims 15-22 are enabled and satisfy the written description requirement (*e.g.*, they comprise a “definition, such as by...physical properties”).

B. Claims 14 – 22 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph

Claims 14-22 have been rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirements. Specifically, the Action alleges that the description of the application would not reasonably convey to one of skill in the art that the Applicants had possession of nucleic acid sequences for any fragment, functional derivative, or allelic variant of the claimed sequences.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, *e.g.*, *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

In view of the current claim 14 directed to nucleic acids having at least 95% identity to SEQ ID NO:1 and claim 15 requiring a fragment, functional derivative, or allelic variant to retain a biological function of an alpha subunit of a sodium channel, and in light of the argument presented above, it is respectfully requested that the Examiner withdraw his rejection of claims 14-22 under 35 U.S.C. § 112, first paragraph.

VI. Rejections under 35 U.S.C. § 102

Claims 14-22 have been rejected as being allegedly “anticipated by Mandel (WO 96/14077...), as evidenced by Mandel (US Patent 6,110,672)” under 35 U.S.C. § 102. Further, Claims 14-19 have been rejected as being allegedly “anticipated by Noda (1986, Nature 320: 188-192), as evidenced by sequence alignment for NCBI Accession Number X03638.”

To anticipate a claim each and every element of the claim must be found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Current claim 14 is directed to SEQ ID NO:1, a complement thereof, or a nucleic acid sequence with at least 95% identity to either of the above, none of which are taught by Mandel or Noda. Therefore claim 14 is not anticipated by the cited art.

Furthermore, the Examiner alleges that there are “large stretches of identity, including the regions from about 479-502 [24 nucleotides] and from about 1016-1041 [26 nucleotides], using Applicant’s numbering system.” Applicant respectfully submits that in view of: (1) the length of SEQ ID NO:1 (8,378 nucleotides), those of the claimed sequences in claim 15 or of a nucleic acid sequence encoding the protein of SEQ ID NO:3, as compared to the short fragments cited by the Examiner taken from **Mandel**; (2) the “overall identity of 42.7 %” with **Mandel**; (3) an alignment of “74% identity between the sequences of **Noda** and SEQ ID NO:1, with “local regions with as much as 86.2% identity”; and (4) the amendment to claim 14 which introduces “having at least 95% identity” that neither Mandel or Noda teach all elements of the claimed invention. Applicant respectfully requests that the Examiner withdraws the rejection of claims 14-19 under 35 U.S.C. § 102 (b).

VII. Rejections under 35 U.S.C. § 103

Claims 14-22 have been rejected as being allegedly unpatentable over **Noda** (1986, Nature 320: 188-192) in view of **Wang** (1997, J. Clin Invest. 99: 1714-1720) under 35 U.S.C. § 103.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

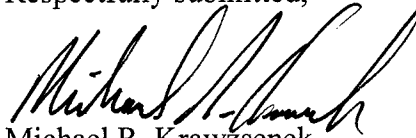
Applicants respectfully submit that, as per §2143.03 of the MPEP, in order “to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” For the reasons set forth above and incorporated here by reference, **Noda** fails to disclose or suggest the nucleic acid of claim 14. Similarly, while **Wang** teaches transfecting vectors comprising nucleic acids encoding sodium channels into cells, it also fails to disclose or suggest the nucleic acids of claims 14 or 16. Therefore, since **Noda** and **Wang** do not disclose or suggest all the limitations of Claims 14 to 28, Applicants respectfully submit that claims 14-22 and newly added 23-28 are patentable over **Noda**, in view of **Wang**, and respectfully submits that the objection be withdrawn.

CONCLUSION

Applicants believe that the present document is a full and complete response to the Action dated August 22, 2006. The present case is in condition for allowance, and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3020 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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